UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,836	10/15/2003	Tooru Morita	50395-234	9853

7590 06/16/2006

MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER	
MENON, KRISHNAN S	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	**Application No.** 10/684,836	**Applicant(s)** MORITA ET AL.
	Examiner Krishnan S. Menon	**Art Unit** 1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 05 June 2006.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-3 and 6-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 and 6-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3 and 6-12 are pending as amended 6/5/06.

Claim Objections

Claim 6 is objected to because of the following informalities: the number '20' between 'unified' and 'body' seems to be extraneous. Appropriate correction is required.

Claim 10 is objected to because of the following informalities: "auction" should be -- suction --. Appropriate correction is required.

Double Patenting

Claim 12 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the variables X, Y and L, and the plot of the ten points; it is unclear; and the claim language does not relate it to any specific structural characteristic of the membrane. Also, RFL is not defined in the claim. Mean maximum fibril length is not clearly defined in the specification or claims as originally filed. This limitation is indefinite because it really does not define any metes and bounds for the claimed structure. Applicant, in the remarks submitted in response to the last office action, indicated that the value (X) corresponds to the pore size. However, the particle size as defined would not correlate to the pore size, if so intended. For the particle size to correlate to the pore size, the particle should be defined as "the ***smallest*** average particle size that would be trapped 90% or greater at 0.1 MPa". Claim language includes any size that would be trapped to 90% or greater. A correction of the claim language to modify 'particle diameter' to "smallest particle diameter" would be deemed new matter since the specification would not support such a change.

For examination, L is taken as the mean fibril length, since the fibrils are characterized by their having length significantly larger than width or diameter; and the values of X and Y are considered as optimizable variables for increasing membrane flux without increasing the fouling.

The "mean maximum length of pores" is also unclear from the claims, but is interpreted as the pore diameter as opposed to the pore length, in the light of specification page 15 lines 21-23, and applicant's arguments of 6/5/06.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP-3221095-B in view of JP 2000-107758 or JP 63-028406.

JP-3221095 teaches a hollow fiber membranes and device as in claims 1-3 and 7-11, and method of making the hollow fiber as in claim 6 and 12. JP-095 teaches fibrillated structure made of PTFE for support tube and rejection layer as claimed, which is obtained by uniaxial or biaxial stretching, laminating the rejection layer to the support tube, rejection layer of PTFE sheet having smaller pore size than the support layer. The support layer is outside and rejection layer is inside the tube for inside to outside filtration in JP-095. See the text of the reference and the figures. Affording unevenness to the outer surface of the expanded PTFE tube with respect to the process is inherent, since the surface would be uneven due to porosity and also due to the stretching (see paragraph 5).

Applicant's claims differ from the teaching of JP-095 in the recitation of the rejection layer on the outside and support inside for outside-in filtration. However, the JP-095 reference teaches that outside-in structures are known in the art (see paragraph 0007), and the teaching of the reference is for specific applications wherein the flow is inside-out. The structure is also otherwise similar – a fibrillated support structure supporting another fibrillated rejection layer. Therefore, the reference actually would anticipate this limitation. The outside-in or inside-out filtration would be obvious to one of ordinary skill in the art since such types of filtrations with hollow fibers are well known in the art, and one would choose to have the filtration layer facing the fluid to be filtered. References JP 63-028406 and JP 2000-107758 teach outside-in filtration, and both references teach fibrillated porous supports and laminated structures. In JP-406, the filtration layer is on the outside similar to the applicant's claims. In JP-758, there is an additional support for the filtration layer from the outside. One would use the teaching of JP-406 or JP-758 in the teaching of JP-095 depending on the type of fluids to be filtered such as blood or water having high amounts of suspended matter for outside-in filtration.

With respect to the limitations in claim 1 as to the relation between the maximum average fiber length (L), particle size (X), RFL and factor (Y), such a relation at best is an optimization process for membrane pore size to the type of fluid to be filtered (such as the suspended matter particle size) for most efficient filtration, such as maximizing the flux, without increasing membrane fouling. For example, consider applicant's comparative example 1. The value of (X) is 0.2 µm, (L) is 15 µm, (L/X) is 75, and the point does not fall within the region defined, as shown in the example. However, for the same membrane, if the (X) value were to be 2.0 µm, (L/X) would be 7.5, and it would fall in the region. If the membrane could trap 0.2 µm particles to above 90%, it would also definitely trap 2 µm particles to above 90%. Thus, this limitation would reduce to just optimizing the membrane usage for a particle size for low fouling and high flux. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

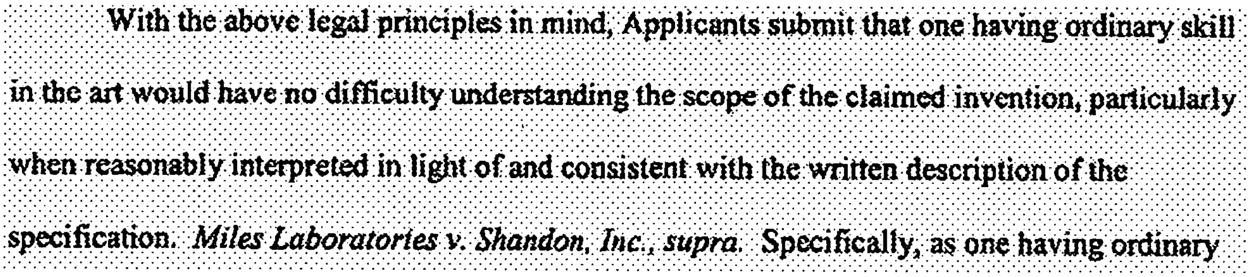
Regarding the ratio of pore diameters between the filtration layer and the support layer, see paragraphs 23 and 24 of the reference. Filtration layer pore size is 0.01 – 10 µm; the support pore size can be optimized as indicated in paragraph 23.

Response to Arguments

Applicant's arguments filed 6/5/06 have been fully considered but they are not persuasive.

In response to the argument that indefiniteness under the second paragraph of 35 USC 112 is **a question of law**, not grammar [*emphasis in original*]: since this argument implies that the claim language is legally correct even if grammatically not so, this part of the indefiniteness rejection is withdrawn.

Applicant's arguments with regard to the second part of the indefiniteness rejection under 35 USC 112, second paragraph, is not persuasive. Applicant's argument:



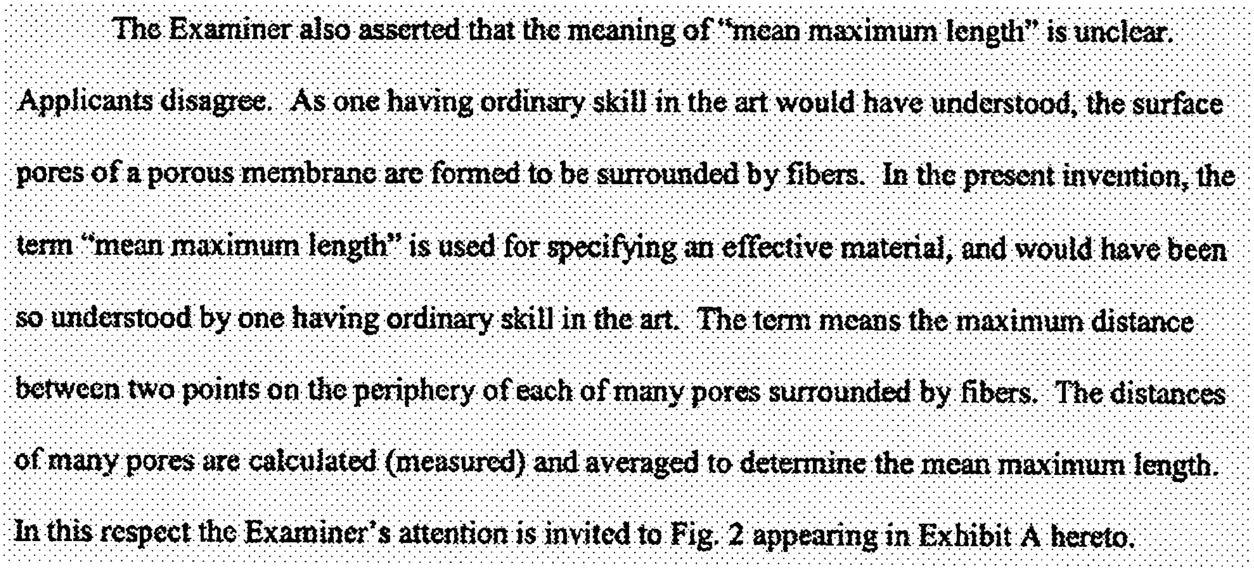
> With the above legal principles in mind, Applicants submit that one having ordinary skill in the art would have no difficulty understanding the scope of the claimed invention, particularly when reasonably interpreted in light of and consistent with the written description of the specification. *Miles Laboratories v. Shandon, Inc., supra.* Specifically, as one having ordinary

is not persuasive, because the claims are given their broadest reasonable interpretation by the PTO.

During examination, the claims must be interpreted as broadly as their terms reasonably allow. > In re American Academy of Science Tech Center, ___ F.3d ___, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.).< This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below)**>; Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004) (Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. Thus, "heating the resulting batter-coated dough to a temperature in the range of about 400oF to 850oF" required heating the dough, rather than the air inside an oven, to the specified temperature.).< One must bear in mind that, especially in nonchemical cases, the words in a claim are generally not limited in their meaning by what is shown or disclosed in the specification. >See, e.g., Liebel-Flarsheim Co. v. Medrad Inc., 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004)(discussing recent cases wherein the court expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment).< It is only when the specification provides definitions for terms appearing in the claims that the specification can be used in interpreting claim language. In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970).

The evidence submitted in the form of the drawings (figure 1 and 2) cannot be accepted as evidence; they only would add new matter. Applicant's interpretation of (X) as pore size is not acceptable, since the claim language and the specification as originally filed do not support this interpretation. In addition, for (X) to be accepted as a measure of the “pore size”, it should be the size of ***the smallest particle*** that would be trapped at 90% or greater trapping ratio. As more clearly stated in the rejection, the claim language can be interpreted to have any particle size that would be trapped at or above 90%; the membrane pore size is a fixed characteristic of the membrane.

The argument:



> The Examiner also asserted that the meaning of “mean maximum length” is unclear. Applicants disagree. As one having ordinary skill in the art would have understood, the surface pores of a porous membrane are formed to be surrounded by fibers. In the present invention, the term “mean maximum length” is used for specifying an effective material, and would have been so understood by one having ordinary skill in the art. The term means the maximum distance between two points on the periphery of each of many pores surrounded by fibers. The distances of many pores are calculated (measured) and averaged to determine the mean maximum length. In this respect the Examiner's attention is invited to Fig. 2 appearing in Exhibit A hereto.

is new matter in its entirety. The specification or the claims as originally filed does not disclose such a definition for “mean of the maximum fibril length (L)”. The figure 2 of the evidence submitted (which cannot be accepted as evidence because it adds new matter) may explain the ‘mean maximum pore size’, but would not explain ‘mean maximum fibril length’.

In response to the argument:

> Specifically, JP '095 relates to a structure in which effective inside-to-outside filtration is performed by providing an inside layer having a smaller pore size to avoid clogging. However, the claimed invention involves more than using 2 layers with different pore sizes. Specifically, in accordance with the claimed invention, the pore size is defined by the particle blocking ability of the whole membrane of a filtration layer, taking into consideration the importance of a filtration surface and, in turn, the fiber length in the surface. Such concepts are not disclosed by JP '095.

Applicant has not correlated pore size to the particle blocking ability as argued, nor does the claim limitation correlate to pore size as shown in the rejection.

Arguments about the supporting references are not commensurate in scope with the rejection; the supporting references were used only to show that outside-in flow is common ion the art. With respect to the motivation to combine, as explained in the rejection, there is no need to combine any references with the primary reference; it teaches all the lements within itself. The only difference of the primary reference with the patentable limitations of the claim is the inside-out filtration structure as opposed to the outside-in structure claimed. However, this limitation is only an obvious difference, if not anticipated by the reference, because such structures are well known in the art.

The argument:

> Specifically, in accordance with the present invention, a dense layer defined by RFL and a pore size is provided as an outside layer serving as a filtration surface, thereby decreasing clogging. When a fluid to be treated contains large particles with high turbidity, most of the large particles irreversibly enter large pores to decrease the apparent pore ratio in the filtration surface. Therefore, as disclosed in the present application, when micro short-fibers are provided on the outer side (filtration surface), particles do not enter the pores and can be easily removed from the membrane surface by a simple operation, such as back washing. This is found to be particularly suitable for treating high-turbidity fluids. This is a novel concept which is alien to the applied prior art.

is not very convincing because, except for defining "RFL", JP-095 teaches the structure claimed. It has a relatively denser, thin, filtration layer and a thicker, open support layer, formed by laminating two layers, the layers being made of stretched PTFE membrane. Applicant has not provided any evidence to show that the primary reference would not have the structure claimed.

The comparative examples in the applicant's specification use only unitary stretched tubes, not the double layer as in the invention. Therefore, the comparative results obtained are not evidence for unexpected results.

Applicant's specification discloses that the fibrous framework surrounding the pore is obtained by uniaxial or biaxial stretching. However it does not disclose how to obtain the "mean maximum fiber length (L)" that would correspond to a (Y) value that would fall within the region bounded by the ten-point plot ***for pore of diameter (X)***, if the particle diameter (X) is interpreted as pore diameter. Specification is not enabling for correlating the mean maximum fiber length (L) with pore diameter (X).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KSMenon 6/12/06
Krishnan S Menon
Examiner
Art Unit 1723